UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., ET AL., Plaintiffs, v. COBALT LABORATORIES, INC., ET AL., Defendants.	
FOREST LABORATORIES, INC., ET AL., Plaintiffs, v. BARR LABORATORIES, INC., ET AL., Defendants.	C.A. No. 08-21-GMS-LPS (Consolidated)
FOREST LABORATORIES, INC., ET AL., Plaintiffs, v. DR. REDDY'S LABORATORIES, INC., ET AL., Defendants.	**PUBLIC VERSION**
FOREST LABORATORIES, INC., ET AL., Plaintiffs, v. ORGENUS PHARMA INC., Defendant.	

AFFIDAVIT OF SATISH SRINIVASAN

I, Satish Srinivasan, declare and state as follows:

1. I am a member of the board of directors of Orgenus Pharma, Inc. ("Orgenus") and am Vice President of Business Development & Operations for Orgenus. I am authorized to make this statement on Orgenus's behalf. I have personal knowledge of the facts asserted herein and, if called as a witness, could and would competently testify to these matters.

2. This declaration supplements my declaration dated March 3, 2008, a copy of which is attached hereto as Exhibit A and incorporated herein by reference. Orgenus is a New Jersey corporation, and its sole office is located in Princeton, New Jersey. Orgenus is the primary business contact for Orchid Chemicals & Pharmaceuticals Ltd. ("Orchid India") for the United States and Canada. The Orchid India web site prominently lists Orgenus as the "Primary Business Contact for US and Canada." *See* Exhibit B. Orgenus has its sole and principal place of business at 700 Alexander Park, Suite 104, Princeton, New Jersey 08540.

3. Orgenus is a wholly-owned subsidiary of Orchid Pharmaceuticals Inc. ("Orchid Delaware"). Orchid Delaware is a Delaware holding company, and is, in turn, a wholly-owned subsidiary of Orchid India, an Indian corporation. [redacted]

4. Orgenus is, and holds itself out to the public as, a separate corporate entity from its parent, Orchid Delaware. Orgenus maintains corporate formalities. Orgenus and Orchid Delaware do not have joint bank accounts. Orgenus keeps its own books and records, and makes its own strategic decisions. Orchid Delaware is not involved in the day-to-day management of Orgenus, nor does it control Orgenus's operations. Orgenus does not represent itself as Orchid

Delaware's agent. Orgenus does not have the power to act for or sign on behalf of Orchid Delaware. Only Orgenus has the power to sign on its own behalf.

5. Orgenus has no offices or employees in Delaware. It does not have a Delaware telephone number. It does not maintain any bank accounts in Delaware. Orgenus does not own or lease any property in Delaware.

6. Orgenus does not advertise products to consumers in the United States generally, or in Delaware in particular. Orgenus does not distribute any products in the United States generally, or in Delaware in particular. Orgenus does not contract with Orchid India's business partners in the United States.

7. Orgenus does not sell any products in Delaware, nor does it solicit sales in Delaware. It does not derive any revenues from Delaware. Orgenus is not registered with the Delaware Secretary of State to do business in Delaware, and is not licensed by the State of Delaware to sell drugs in the State.

8. To the best of my knowledge, Orgenus has not conducted business with any entity located in Delaware.

9. Orgenus has never commenced any legal action or proceeding in Delaware, nor has it previously been named a defendant in any action in Delaware.

10. [redacted]

[redacted] None of the services provided by Orgenus to Orchid India are involved with Delaware or entities located in Delaware.

11. Orgenus serves as Orchid India's U.S. regulatory agent for FDA matters. Orchid India named Orgenus its U.S. regulatory agent for purposes of submitting documents regarding generic memantine hydrochloride drug products to the FDA.

[redacted]

15. Orgenus publicly disclosed that it is Orchid India's regulatory agent in the U.S. in a Suitability Petition filed on behalf of Orchid India with the FDA on May 18, 2007, regarding a proposed new formulation for generic memantine hydrochloride drug products. *See* Exhibit D.

16. Orgenus and Orchid India are presently involved in unrelated litigation in the District of New Jersey arising from the submission of other ANDAs. Orgenus has not challenged personal jurisdiction in that district.

I declare under penalty of perjury and the laws of the United States that the foregoing is true and correct.

Dated: June 18, 2008

Satish Srinivasan

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on June 26, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on June 26, 2008, the attached document was Electronically Mailed to the following person(s):

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869316 / 32657 (Cons.)

EXHIBIT A

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY

EXHIBIT B

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e-mail: corporate@orchidpharma.com

R&D Centres

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Plot Nos. B21-23 & B31-33
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Manufacturing Facilities

API

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EXHIBIT C

THIS EXHIBIT HAS BEEN
REDACTED IN ITS ENTIRETY

EXHIBIT D

7232 7 MAY 18 A10:18

Orgenus

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUITABILITY PETITION

Dear Sir or Madam:

Orgenus Pharma, Inc. hereby submits this Suitability Petition on behalf of Orchid Healthcare as its US Agent.

This petition is submitted, in quadruplicate, pursuant to 21 CFR § 10.20 and § 10. 30, as provided for in 21 CFR § 314.93 and section 505(j)(2)(C) of the Federal Food, Drug and cosmetic Act, to request the commissioner of the Food and Drug Administration to declare that the drug product Memantine Hydrochloride Orally Disintegrating Tablets 5 mg and 10 mg are suitable for submission as an abbreviated new drug application (ANDA).

Action Requested

The petitioner requests that the commissioner of the Food and Drug Administration declare that Memantine Hydrochloride Orally Disintegrating Tablets 5 mg and 10 mg are suitable for submission as an ANDA. The reference listed drug products (RLDs) upon which this petition is based are Namenda ® Tablets 10 mg & 5 mg (NDA # 021487) and Oral Solution 2 mg / ml (NDA # 021627), manufactured by Forest Pharmaceuticals Inc. (See copy of the page from the current Electronic Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, Attachment 1). The petitioner seeks a change in dosage form (from the approved dosage forms of tablets and solution to an orally disintegrating tablets) from that of the RLD products.

Statement of Grounds

The proposed drug product, Memantine Hydrochloride Orally Disintegrating Tablets, is presented for administration by placing on the tongue, which will disintegrate in a matter of seconds and swallowing the disintegrated tablet with or without water.

The Orally Disintegrating Tablets would be a viable alternative to both of the currently marketed dosage forms, Tablets and Oral Solution, due to the following advantages:

- Convenient for patients who have difficulty in swallowing tablet dosage form.
- Unit dose dispensing of drug (in comparison with solution form).
- Does not require a dosing device as in solution form.

2007P-0203 CP1

- Ease of carrying (in comparison with a bulky solution container).
- Ease of administration. Administration with water is not required.

The proposed product will differ only in dosage form. The indications, strengths, route of administration, intended patient population and recommendations for use will remain the same as of the RLD products. The proposed product will be formulated so as to be bioequivalent to current tablet formulation (RLD), marketed by Forest Pharmaceuticals Inc. The proposed product will contain inactive ingredients that are generally recognized as safe (GRAS) and at levels previously approved by USFDA. Therefore there will be no difference between the safety and efficacy of the proposed product and RLD products.

The proposed product will be labeled in accordance with the approved labeling of RLD products upon which this petition is based. Any difference in labeling will relate only to the differences in dosage forms. The indications, warnings, dosage, route of administration and intended patient population will remain the same as that of RLD products.

Therefore the petitioner requests the commissioner to find that a change in dosage form from Tablets and Oral Solution to Orally Disintegrating Tablets should raise no questions of safety or effectiveness and the Agency should approve the petition.

Pediatric Use Information

The petitioner is aware that, according to the Pediatric Research Equity Act (PREA) of 2003, which amended the FDC Act, a pediatric assessment is required for a new proposed product with a new dosage form.

The petitioner hereby requests that a waiver from the conduct of pediatric studies under 21 U.S.C. § 355c(a)(4)(A) pursuant to 21 CFR § 314.55(c)(2)(i) be granted for the approval of this petition to permit a subsequent ANDA filing. The request for waiver is justified as the drug or biological product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients and is not likely to be used in substantial number of pediatric patients.

For the aforementioned reasons, the undersigned requests that the Commissioner grant this petition and authorize submission of an ANDA for Memantine Hydrochloride Orally Disintegrating Tablets 5 mg and 10 mg.

Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR § 25. 31.

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Phone: 609-951-2209
Fax: 609-951-2213

Orgenus

Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the agency.

Certification

The undersigned certifies that to the best of his knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which is unfavorable to the petition.

Sincerely,

Satish Srinivasan
Director, Business Development & Operations

Attachments:

1. Approved Drug Products with Therapeutic Equivalence Evaluations
2. Draft labeling proposed for Memantine Hydrochloride Orally Disintegrating Tablets
3. Labeling for the RLD, Namenda ® Tablets / Oral Solution

Namenda ® is registered Trademark of Forest Pharmaceuticals Inc.

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